REMARKS

Disposition of Claims

Upon entry of the foregoing amendments, claims 1-14 and 19 will remain pending in the application and stand ready for further action on the merits. A Request for Continued Examination (RCE) of the application has been filed herewith. Claim 1 has been amended herein to clarify that bone repair material is in the form of putty as described throughout the Specification, particularly at Paragraphs 0018, 0030-0035, and Examples.

Claim Rejections under 35 U.S.C. §103

The Office Action first rejects claims 1, 3-6, and 8 under 35 U.S.C. §103(a) as being unpatentable over Gertzman, US Patent 6,030,635 ("Gertzman"). In response, Applicants respectfully submit the disclosure in Gertzman does not render the claimed invention (as recited in amended claims 1, 3-6, and 8) prima facie obvious for the reasons discussed below.

Applicants agree with the Examiner that Gertzman discloses a malleable putty that is applied to bone defect sites for promoting new growth at the site. As the Examiner points out, the Gertzman putty comprises a mixture of demineralized, osteogenic bone powder having a particle size in the range of about 100 to about 850 microns in a carrier solution comprising a high molecular weight carrier in water. Suitable carriers are described as being selected from hyaluronic acid, chitosan, dextran, and the pluronic block copolymers of polyethylene oxide and polypropylene oxide having a molecular weight in the range of 500,000 to 3,000,000 Daltons. The Gertzman putty, however, contains only about 25 to about 40% bone powder. (See abstract and col. 5, lines 24-29 and examples I-XII.)

There are significant differences between the putty material described in Gertzman and the bone repair putty of the present invention. Particularly, as recited in the above amended claims, the bone particulate is present in Applicants' putty in an amount of at least about 50% by weight. This high concentration of bone particulate is important, because it helps promote more bone formation as discussed at Paragraph 0026 of the Specification. Moreover, even at these relatively high concentrations, Applicants' putty has good viscosity and handling properties. This allows a clinician to mold and shape the material to the desired structure at the bone repair site. The putty has good dimensional stability and maintains the high level of particulate in suspension. The bone particulate is not allowed to migrate away from the bone repair site and

this enhances new bone growth. In sharp contrast, when the amount of bone particulate in the Gertzman formulation is increased to 50% concentration or greater, the putty tends to dry out and become grainy. The Gertzman formulation does not have good molding or forming properties at these concentrations.

It is respectfully submitted that a person of ordinary skill in the art looking at the teachings in Gertzman and applying common sense, would not reasonably consider adding bone particulate at concentrations of 50 wt.% and greater. There is absolutely no basis in the teachings of Gertzman for making such putty material. At bone powder concentrations of 50%, the Gertzman putty materials show poor formability and are simply unacceptable. Gertzman repeatedly provides evidence of these problems. (See Examples II [50% particulate conc.], III [50%], XII [50%], and XIII [50%].)

The Examiner seems to suggest that the particle size distribution of the particulate and molecular weight of the carrier are critical variables for making bone repair putty. And, effective putty materials can be prepared by simply using ingredients having the correct particle size and molecular weight. Applicants respectfully submit that their putty materials are fundamentally different from the Gertzman materials. And, it is not simply a matter of routine experimentation. In Gertzman, two different putty materials were prepared, each sample using freeze dried cortical allograft bone particulate having a particle size of 420-850 microns and chitosan carrier having a molecular weight (col. 5, lines 15-17) of 2.0×10^5 Daltons In Example XI, the putty at 33% particulate concentration showed "good formability properties." But, in Example XII, the same putty at 50 wt.% concentration showed "poor formability properties."

Gertzman provides no guidance or suggestion as to how to make bone repair putty having good handling and molding properties at $\geq$ 50% concentrations. Merely trying different ingredients and optimizing their amounts is not enough. Many different factors were considered in making Applicants' materials. Gertzman does not provide the skilled artisan with any reasonable expectation that such materials would even work. Thus, a skilled artisan looking at Gertzman would only be motivated or guided to make the presently claimed putty material by looking at Applicants' own specification. It is respectfully submitted that such hindsight reconstruction of the claimed invention to render it prima facie obvious is not permitted.

Concerning the disclosure in Gertzman for a composition comprising hyaluronic acid and a concentration up to 75% by weight of bone particles at column 5, lines 57-61, it is respectfully

submitted that this refers to a sponge sheet or mat of bone which is cut to shape by the dental surgeon. A sponge sheet or mat has a completely different structure and form than a putty material which is molded and shaped by hand to fit the geometry of the bone repair site. Claims 1-14 and 19 in the instant application have been amended to clarify that the bone repair material is in putty form. Gertzman clearly distinguishes between the different forms of material: malleable putty compositions, flowable gels, and sponge sheets and mats. As discussed above, Gertzman explicitly teaches away from the present invention asserting that putty materials containing bone powder at concentrations of 50% have poor molding and handling properties.

Secondly, the Office Action rejects claims 1-14 and 19 under 35 U.S.C. §103(a) as being unpatentable over Gertzman in view of Tofe, US Patent Application Publication No. US2003/0143283 ("Tofe"). It is respectfully submitted that the presently claimed invention, as recited in amended claims 1-14 and 19, is not prima facie obvious over the disclosures in Gertzman and Tofe for the reasons discussed below.

The Gertzman reference is discussed above, and these points will not be repeated for the sake of brevity. It is believed that amended claims 1-14 and 19 are patentable over Gertzman. Turning to Tofe, this reference refers to a bone repair composition comprising non-human bone material such as granulated or powdered bovine or other animal bone suspended in a hydrogel carrier such as high molecular weight hyaluronate. Tofe readily admits that the Gertzman material can be used in the Tofe bone repair composition (See Paragraph 0013). Tofe merely adds that his composition may further contain a polypeptide sequence as described in the Bhatnagar patents to help promote bone growth. However, there is nothing in the disclosure of Tofe which suggests how to add the polypeptide sequences to the composition. Tofe fails to teach whether the polypeptide sequences are irreversibly bound to the bone particulate or if they are added unattached. Moreover, there is nothing in Tofe suggesting the concentration of bone particulate, carrier material, or polypeptide sequences. There is no information provided about the molecular weights or densities of the components. Tofe is completely silent as to these points. There is no teaching or any examples describing how to mix or formulate the composition. Tofe refers to the general disclosures in the Gertzman and Bhatnagar patents but does not add anything new.

Thus, even if a person of ordinary skill in the art looked to the disclosure in Tofe and combined it with the teachings in Gertzman, the present invention still would not be obvious.

Accordingly, it is respectfully requested that the rejection of claims 1-14 and 19 under 35 U.S.C. §103(a) (as amended) over Tofe and Gertzman be withdrawn.

Conclusion

In summary, Applicants submit that claims 1-14 and 19 (as amended) are patentable and each of the Examiner's rejections and objections has been overcome. Accordingly, Applicants request favorable consideration and allowance of amended claims 1-14 and 19. The Commissioner is hereby authorized to charge any additional fee required in connection with the filing of this paper or credit any overpayment to Deposit Account No. 04-0780. Should there be any outstanding matter that needs to be resolved in the present application; the Examiner is invited to contact the undersigned at the telephone number provided below.

Respectfully submitted,

DENTSPLY International Inc.

By: Daniel W. Sullivan

Daniel W. Sullivan
Reg. No.: 34,937
Tel.: (717) 849-4472
Fax: (717) 849-4360

Dated: MARCH 11th, 2008

Attachments: Petition for Extension of Time
Request for Continued Examination